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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/761,159	01/20/2004	Biten K. Kathrani	END-5255	2562
27777	7590	09/21/2006	EXAMINER	
PHILIP S. JOHNSON JOHNSON & JOHNSON ONE JOHNSON & JOHNSON PLAZA NEW BRUNSWICK, NJ 08933-7003			SMITH, PAUL B	
			ART UNIT	PAPER NUMBER
			3763	

DATE MAILED: 09/21/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>
	10/761,159	KATHRANI ET AL.
	<b>Examiner</b>	<b>Art Unit</b>
	Paul B. Smith	3763

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 20 January 2004.  
 2a) This action is FINAL.                    2b) This action is non-final.  
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-26 is/are pending in the application.  
 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
 5) Claim(s) \_\_\_\_\_ is/are allowed.  
 6) Claim(s) 1-26 is/are rejected.  
 7) Claim(s) \_\_\_\_\_ is/are objected to.  
 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.  
 10) The drawing(s) filed on 6/25/2004 is/are: a) accepted or b) objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All    b) Some \* c) None of:  
     1. Certified copies of the priority documents have been received.  
     2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
     3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date: _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>1/20/2004 5/9/2005</u> .                                      | 6) <input type="checkbox"/> Other: _____                          |

**DETAILED ACTION**

***Information Disclosure Statement***

1. The information disclosure statements (IDS) submitted on 1/20/2004 and 5/9/2005 are acknowledged. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the examiner considers the references cited therein.

***Claim Rejections - 35 USC § 112***

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 19-21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

4. Claim 19 recites the limitation "cannula" and "cannula extension" in the second line of the claim. There is insufficient antecedent basis for this limitation in the claim.

***Claim Rejections - 35 USC § 102***

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1-2, 4, 6-7, 10-12, 14, and 17 are rejected under 35 U.S.C. 102(b) as being anticipated by Dorsey, III ('710).

7. Dorsey, III discloses a medical device comprising a first elongate member (12), a second elongate member (13), and an attachment means (not referenced). The attachment means comprises tabs (20) disposed on the outer surface of the first elongate member and a groove (36) disposed on the inner surface of the second elongate member. The first member has an open distal end with a pointed tip adapted to pierce a membrane. The first member is an extension to the second member. The second member is a cannula. The first member further comprises a plurality of openings through the wall. The second member can comprise a plurality of openings through the wall. (See Figure 1-3 and 15-16)

8. It appears that Dorsey, III reasonably discloses every element of claims 1-2, 4, 6-7, 10-12, 14, and 17.

9. Claim 25 is rejected under 35 U.S.C. 102(b) as being anticipated by Luther *et al.* ('848).

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10. Luther et al. discloses a medical device comprising a first hollow elongated member (14), a second hollow elongated member (32), a cap (26), and a sleeve (10). The first hollow elongated member is releasably attached to the second hollow elongated member. (See Figure 1-3)

11. It appears that Luther et al. reasonably discloses every element of claim 25.

12. Claim 26 is rejected under 35 U.S.C. 102(b) as being anticipated by Gerber et al. ('624).

13. Gerber et al. discloses a medical device comprising a vacuum device (40), a multi-component device (not referenced), a first member (10), and a second member (20). (See Figure 15)

14. It appears that Gerber et al. reasonably discloses every element of claim 26.

#### ***Claim Rejections - 35 USC § 103***

15. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

16. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

17. Claims 3 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dorsey, III ('710) in view of Galt *et al.* ('775).

18. Dorsey, III discloses a medical device comprising a first elongate member (12), a second elongate member (13), and an attachment means (not referenced). The attachment means comprises tabs (20) disposed on the outer surface of the first elongate member and a groove (36) disposed on the inner surface of the second elongate member. (See Figures 1-3)

19. Dorsey, III fails to disclose a first member with a closed distal tip or a second member with a beveled tip.

20. Galt *et al.* teaches a medical device comprising a variety of tips for an inner hollow elongate member, such as a closed distal tip (116) and a outer elongated member with a beveled tip (112). (See Figure 12)

21. It would have been obvious to one of ordinary skill in the art to modify the disclosure of Dorsey, III with the teachings of Galt *et al.* to provide a first elongate member with a closed distal tip and a second elongate member with a beveled tip.
22. Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Dorsey, III ('710) in view of Santangelo *et al.* ('242).
23. Dorsey, III discloses a medical device comprising a first elongate member (12), a second elongate member (13), and an attachment means (not referenced). The attachment means comprises tabs (20) disposed on the outer surface of the first elongate member and a groove (36) disposed on the inner surface of the second elongate member. (See Figure 1-3)
24. Dorsey, III fails to disclose a first member comprising a relatively flexible distal end portion.
25. Santangelo *et al.* teaches an inner elongate member (16) which may be a flexible construction. (See Figure 1 and Column 4 Lines 1-2)
26. At the time of the invention, it would have been obvious to one of ordinary skill in the art to modify the disclosure of Dorsey, III with the teachings of Santangelo *et al.* to provide an inner elongate member that has a relatively flexible distal end portion.

27. Claims 8-9 and 19-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dorsey, III ('710) in view of Olsen *et al.* ('308).

28. Dorsey, III discloses a medical device comprising a first elongate member (12), a second elongate member (13), and an attachment means (not referenced). The attachment means comprises tabs (20) disposed on the outer surface of the first elongate member and a groove (36) disposed on the inner surface of the second elongate member. (See Figure 1-3)

29. Dorsey, III fails to disclose a cap that is attachable to either the first member or second member with a substantially airtight seal and has an opening therethrough.

30. Olsen *et.al.* teaches a medical device with a cap (148) that is attached to an inner elongate member and forms a substantially airtight seal therewith. The cap is further taught to include an opening (149) therethrough. (See Figure 5)

31. It would have been obvious at the time of the invention to one of ordinary skill in the art to modify the disclosure of Dorsey, III with the teachings of Olsen *et al.* to provide a cap with an opening therethrough and forms a substantially airtight seal when attached to either first or second elongate member.

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32. Claims 15-16 and 22-24 rejected under 35 U.S.C. 103(a) as being unpatentable over Dorsey, III ('710) in view of Sommerich ('310).

33. Dorsey, III discloses a medical device comprising a first elongate member (12), a second elongate member (13), and an attachment means (not referenced). The attachment means comprises tabs (20) disposed on the outer surface of the first elongate member and a groove (36) disposed on the inner surface of the second elongate member. (See Figure 1-3)

34. Dorsey, III fails to disclose a sleeve with a sealing surface that is coated with a medicinal substance.

35. Sommerich teaches a medical sleeved that comprises a sealing surface and is adapted to provide a substantially airtight seal between the patient and an inserted tube. (See Figure 2) The sleeve is coated with an antibacterial substance. (See Claim 25)

36. To one of ordinary skill in the art at the time of the invention, it would have been obvious to modify the disclosure of Dorsey, III with the teachings of Sommerich to provide a sleeve with an medicinal coating and adapted to prevent gas leakage through an incision.

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37. Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over Dorsey, III ('710) in view of Purdy *et al.* ('882).

38. Dorsey, III discloses a medical device comprising a first elongate member (12), a second elongate member (13), and an attachment means (not referenced). The attachment means comprises tabs (20) disposed on the outer surface of the first elongate member and a groove (36) disposed on the inner surface of the second elongate member. (See Figure 1-3)

39. Dorsey, III fails to disclose a first and second member that has a generally transparent wall.

40. Purdy *et al.* teaches a medical device that comprises a generally transparent wall such that the presence of blood or other fluids is visible to the practitioner. (See Column 5 Lines 35-39)

41. It would have been obvious at the time of the invention to one of ordinary skill in the art to modify the disclosure of Dorsey, III with the teachings of Purdy *et al.* to provide inner and outer elongate members that are substantially transparent.

42. Claim 18 rejected under 35 U.S.C. 103(a) as being unpatentable over Dorsey, III ('710) in view of Hildwein *et al.* ('156).

43. Dorsey, III discloses a medical device comprising a first elongate member (12), a second elongate member (13), and an attachment means (not referenced). The attachment means comprises tabs (20) disposed on the outer surface of the first elongate member and a groove (36) disposed on the inner surface of the second elongate member. (See Figure 1-3)

44. Dorsey, III fails to disclose first and second members that comprise a non-circular cross section.

45. Hildwein *et al.* teaches a medical device comprising an inner and an outer elongate member that comprises a non-circular cross section. (See Figure 10)

46. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the disclosure of Dorsey, III with the teachings of Hildwein *et al.* to provide inner and outer elongate members that comprise a non-circular cross section.

### ***Conclusion***

47. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Paul B. Smith whose telephone number is 571-272-6022. The examiner can normally be reached on 8 am - 4 pm.

48. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

49. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Paul B Smith  
Examiner  
Art Unit 3763

PBS  
September 15, 2006



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